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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,290	08/03/2001	David M. Goldenberg	329572	5316

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MINNEAPOLIS, MN 55402-3901

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary****Application No.**

09/921,290

**Applicant(s)**

GOLDENBERG, DAVID M.

**Examiner**

Alana M. Harris, Ph.D.

**Art Unit**

1643

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/30/2004; 03/14/2005</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment and Arguments***

1. Claims 1-48 are pending.

Claims 1 and 30 have been amended.

Claims 1-48 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Priority***

3. Applicant's claim for domestic priority under 35 U.S.C. 112 is acknowledged. Applicant has informed the Examiner about the order from which priority should follow, see page 8 of Remarks submitted March 14, 2005. The Examiner acknowledges this, however that does not change the priority date afforded Applicant's instant claims. As noted in the first action on the merits (FAOM) mailed December 16, 2003 the prior applications *only* contemplate the treatment of B-cell disorders (including plasma-cell disorders) and not T-cell or mast-cell disorders, nor treatment of animals. Hence, the priority afforded the examined claims is the effective filing date of the instant application, August 3, 2001.

Art Unit: 1643

***Oath/Declaration***

4. The oath or declaration is no longer defective because Applicant has submitted another on March 14, 2005 that contains the proper information.

***Withdrawn Grounds of Objection***

***Claim Objections***

5. Claim 30 is no longer objected to because it properly depends from claim 26.

***Withdrawn Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 1, 2, 8, 9, 11, 12, 16, 19-22, 23, 24, 26 and 44 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,776,456 (filed June 7, 1995) is withdrawn in light of Applicant's amendment to claim 1.

***Maintained and New Grounds of Rejections***

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 16-19, 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1643

a. Claims 16, 18, 19 and 39 cite "domestic animal", however independent claim 1 lacks antecedent bases for the recitation.

***Claim Rejections - 35 USC § 103***

9. The rejection of claims 1-5, 7-9, 11, 12, 15-29, 32-35 and 37-46 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of U.S. Patent number 5,837,242 (May 14, 1996) and Rybak et al. (Proc. Nat. Acad. Sci. USA 89: 3165-3169, April 1992) is maintained.

Applicant set forth the criteria and requirements for making a *prima facie* case of obviousness. Applicant avers the '456 patent does not suggest or describe any method for treating the animals listed in the newly amended claim 1 and the secondary references do not make up the alleged deficiencies. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As noted in previous actions patent #5,776,456 teaches "...therapeutic methods designed for the treatment of B cell disorders, and in particular, B cell lymphomas", which is a B cell malignancy and these methods are applicable to primates and are not limited to humans, see column 5, lines 7-23. And while U.S. Patent '456 does not teach a method for treating a B-cell or plasma-cell disorder in the animals listed in newly amended claim 1, there is suggestion in the patent to apply the taught method to additional animals. Hence, meeting the first requirement cited by Applicant in criteria necessary for a *prima facie* case of obviousness. Both the patent and Rybak provide impetus to modify and manufacture immunologically active antibodies for effective

Art Unit: 1643

targeted therapeutic tumor treatment, see entire Rybak paper and patent, section V. of column 31. And both documents note the successful use of recombinant molecules for the destruction of tumor cells, see both documents. Consequently, the Examiner has met all three standards for making a prima facie case of obviousness and the rejection is maintained for the reasons of record and those set forth herein.

10. The rejection of claims 1-27, 31 and 34-48 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of U.S. Patent 6,217,869 (filed September 5, 1997) is maintained.

Applicant avers the '456 patent does not suggest or describe any method for treating the animals listed in the newly amended claim 1 and the secondary references do not make up the alleged deficiencies. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

For the reasons of record and established in the previous 103(a) rejection the instant rejection is maintained.

11. The rejection of claims 1, 2, 8, 9, 11, 12, 16, 19-22, 23, 24, 26, 30, and 44 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of Javid et al. (J. Clin Invest. 31(6): 604-10, June 1952) is maintained.

Applicant avers the '456 patent does not suggest or describe any method for treating the animals listed in the newly amended claim 1 and the secondary references

Art Unit: 1643

do not make up the alleged deficiencies. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

For the reasons of record and established in the previous 103(a) rejection the instant rejection is maintained.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

Art Unit: 1643

(571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
12 January 2007